IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent Application of
Timothy P. COLEMAN et al.
Serial No.: 09/495,947
Filed: 2 February 2000

Group Art Unit: 1633
Examiner: C. Drabik

For: ADVANCED ANTIGEN PRESENTATION PLATFORM

DECLARATION OF TIMOTHY P. COLEMAN, Ph.D., UNDER 37 C.F.R. § 1.132

Commissioner for Patents
Washington, D.C. 20231

Sir:

I, Timothy P. Coleman, Ph.D., declare that:

1. I am an inventor of the inventions disclosed and claimed in the United States Patent Application Serial No. 09/495,947 filed on 02 February 2000 (hereinafter "Application") and I am familiar with the subject matter claimed therein. I am one skllled in the art to which the Application pertains; a copy of my CV is attached as Exhibit 1. The nature of the claimed invention is drawn, *inter alia*, to compositions for vaccination against cancer.

2. I have read and am familiar with the Office Action mailed 23 July 2001 (Paper No. 12) and the Examiner's rejection of claims 2, 3, 5, 6, 8-13, 14-16, and 21-29 under 35 U.S.C. § 112, ¶1, based on the Examiner's contention that the inventions as claimed could not be practiced by one skilled in the art, at the time of filing of the Application, without significant and undue experimentation. It is my opinion that one skilled in the art would be able to make and use the inventions of the subject claims, in view of the Application, without undue experimentation.

3. This is evidenced by the results reported in the Experimental Summary attached as Exhibit 2, entitled "Analysis of the Immune Response to ΔDmuc35-DHBcAg

and control antigens in BALB/c mice." This Experimental Summary reports experiments supervised and conducted by me and my researchers using the compositions and methods of the subject claims, which were made and used based on the disclosure of the present Application, that demonstrate the stimulation of an immunogenic response in mice using the compositions of the present invention.

4. Exhibit 2 reports the cloning of two copies of the VNTR of Muc1, a protein expressed on the surface of numerous types of cancer cells, into a surface accessible region of a modified version of the Duck hepatitis core antigen (DHBcAg) known as ΔDmuc35-DHBcAg. This construct was produced following the methodology taught in the Application on, for example, pages 13-14. VNTR is a cancer hapten within the genus of cancer haptens described in the Application on, for example, pages 16-17. Exhibit 2 discusses the use of the resulting protein construct to induce an immunogenic response. Importantly, Exhibit 2 shows that antibodies generated in mice immunized with ΔDmuc35-DHBcAg effectively bind Muc1 when Muc1 is found in its native conformation within the Muc1 positive human breast cancer cell line MCF-7. The compositions and methods successfully used in the experiments reported in Exhibit 2 were made and used by one skilled in the art in view of that which was disclosed in the Application.

5. My opinion that one skilled in the art would be able to make and use the inventions of the subject claims, in view of the Application, without undue experimentation is also evidenced by the results reported in the Experimental Summary attached as Exhibit 3, entitled "Analysis of the Immune Response comparing AAPP-MUC1 and KLH-MUC1 in BALB/c mice." This Experimental Summary reports experiments supervised and conducted by me and my researchers using the compositions and methods of the subject claims, which were made and used based on the disclosure of the present Application, that demonstrate the stimulation of an immunogenic response in mice using the compositions of the present invention.

6. Exhibit 3 reports the construction of AAPP-MUC1(16), a protein construct comprising the VNTR of mucin, a protein expressed on the surface of numerous types of cancer cells, and the DHBc protein. This construct was produced following the methodology taught in the Application on, for example, pages 13-14. VNTR is a cancer hapten within the genus of cancer haptens described in the Application on, for example, pages 16-17. Exhibit 3 discusses the use of AAPP-MUC1(16) to induce an immunogenic response. Importantly, Exhibit 3 shows that a strong immune response to the AAPP-

MUC1(16) protein construct develops in organisms injected with the protein without the use of an adjuvant, including the stimulation of IgM, IgG, IgG2a, and IgG2b antibodies. The compositions and methods successfully used in the experiments reported in Exhibit 3 were made and used by one skilled in the art in view of that which was disclosed in the Application.

7. All the statements made herein of my knowledge are true, and all statements made on information and belief are believed to be true; and further, these statements are made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both; and any such willful false statements may jeopardize the validity of any patent issuing on the above-identified application.

DATE: 1/18/02

BY: Timothy P. Coleman

Timothy P. Coleman, Ph.D.

TIMOTHY P. COLEMAN

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OBJECTIVE

A proven leader with a strong competency in biotechnology and business start-up. Primary therapeutic areas of knowledge in cardiovascular and immunotherapy. Experience encompasses a variety of functions including general management, R&D operations, finance, directorship, and grantsmanship. Educational experience includes baccalaureate and doctoral degrees in biochemistry. The ideal work environment would be in biopharmaceutical industry and require entrepreneurial leadership to establish a focused team to develop and execute a winning strategy.

RESPONSIBILITIES

- Executive Management
- Fund Raising and Financial Stewardship
- R&D Planning & Strategy
- Directorship
- Intellectual Property Development
- Business Development
- Operations & Personnel

EXPERIENCE

PRESIDENT, COO, DIRECTOR AND FOUNDER

10-00 through present BioCache Pharmaceuticals, Inc Richmond, VA

BioCache Pharmaceuticals, Inc. is a biopharmaceutical company focused on becoming a world leader in the development of proprietary products for the treatment and prevention of immunological disease in two key areas – cancer and infectious diseases. Responsibilities focused on securing institutional venture financing, directing the expansion of R&D activities of the core immunology technology, and developing multiple external relationships. Leadership in this role led to the identification and recruitment of several high profile university collaborators to help establish BioCache as world leader in immunological biopharmaceutical product development.

Reporting

Chief Executive Officer & Board of Directors

Accomplishments

Business Development

- Initiated four therapeutic research collaborations with major Universities:
  - Brigham and Woman's Hospital
  - Memorial Sloan Kettering
  - Two with Medical College of Virginia's Massey Cancer Center

Financial

- Raised $500,000 in venture capital during May of 2001 bring the total amount raised to date to $1.7 million
- Prepared and received Board approval for 2001 operating budget
- Presented the Company to nationally recognized venture capital firms

Operations

- Co-inventor and author of a pending patent application in the field of immunology
- Directed all aspects of planning for the Company's new facility
- Strategic expansion of the Company's immune therapeutic programs

CO-FOUNDER, PRESIDENT, CEO, AND DIRECTOR

11-97 through 9-00 BioCache Pharmaceuticals, LLC Richmonnd, VA

BioCache Pharmaceuticals, LLC is an early stage biopharmaceutical company focused on becoming a world leader in the development of proprietary products for the treatment and prevention of immunological disease in three key areas – cardiovascular, cancer, and infectious diseases. Responsibilities as the initial leader of this start-up entity were focused on designing a fundable business concept around a core of technology, show proof-of-principal of those product opportunities, and assemble the resources necessary to build shareholder value. Leadership in this role led to the recruitment of a pharmaceutical industry senior executive to help BioCache achieve it's corporate goal of becoming a world leader in immunological biopharmaceutical product development.

REPORTING

Board of Directors

ACCOMPLISHMENTS

Operations

- Co-inventor and authored two pending patent applications in the areas of immunotherapeutics and cardiovascular therapies
- Developed and implemented a standard operating procedure (SOP) policy to develop consistent methods for data acquisition and storage, biopharmaceutical production and storage, and product assay development
- Instituted a weekly goals program to track performance, increase accountability, and research productivity
- Directly recruited three members of the Board of Directors, including the Chairman, with experience in finance, business law, and biotechnology/pharmaceutical experience
- Developed a proactive intellectual property program during the initial start-up phase of the Company
- Developed R&D programs to provide pre-clinical data for two product areas immunotherapy and cardiovascular disease
- Recruited a highly motivated and knowledgeable scientific staff growing the company to ten technical associates (5 Ph.D., 2 M.D., 2 M.S. & a B.S.) in less than two years
- Instrumental in recruiting a pharmaceutical industry senior executive to become the Company's president and CEO (formally of Monsanto)

Financial

- Negotiated a peptide development contract with PXP, LLC for $120,000 that resulted in the start-up capital for the Company
- Authored the Company's business plan that successfully raised $1.2 million in seed and follow on capital
- Co-authored a Small Business Technology Transfer (STTR) that was awarded a $100,000 for the development of a Hepatitis C vaccine
- Increased the number of investors in the Company from one (1) to eleven (11) in two years
- Developed and received Board approval for pro-forma budgets for years one

through seven
- Presented the Company to investors and investor forums

Business Development
- Established professional business relationships with legal, accounting, and business development firms ensuring the proper corporate records and documentation are correctly maintained
- Negotiated a license with a major university for core technology and rights to future technology from specific university researchers
- Developed strong ties between the Company and a major University including:
  - Established a plan for shared use of equipment
  - Established the necessary relationships to have animal protocols approved by the appropriate University committees
- Established a relationship with the Intellectual Property Foundation to review additional technologies that may have commercial value and become potential licensee candidates of the Company

ADJUNCT ASSISTANT PROFRESSOR

1999 through Present Virginia Commonwealth University Richmond, VA

Medical College of Virginia, Department of Medicinal Chemistry, Institute for Structural Biology and Drug Discovery

MEMBER

2001 through Present Massey Cancer Center Richmond, VA

Virginia Commonwealth University, Medical College of Virginia
Unanimously Elected Member
The Massey Cancer Center's mission is to serve the Commonwealth of Virginia and the nation as an internationally recognized center of excellence in research, education, and patient care. Members are dedicated to improving the quality of human life through the development of effective means for the prevention, control, and ultimately the cure of cancer. The core of this mission is the facilitation of interdisciplinary cancer research to harness the significant scientific and clinical resources of Virginia Commonwealth University and the Medical College of Virginia.

CONSULTANT

2000 through present Tall Oaks Capital Charlottesville, VA

Review and provide written technical and business assessment on the commercial feasibility of life science technologies in biotechnology business plans.

DOCTORAL TRAINING

1993 to 1998 Medical College of Virginia Richmond, VA
Identification of the cis and trans-factors involved in rat calcitonin/CGRP splicing
- Advisor: James Roesser, Ph.D.

EDUCATION

Ph.D.	**1993-1998**	**Medical College of Virginia** Biochemisty	**Richmond, VA**
B.S.	**1989-1993**	**Worcester Polytechnic Institute** Biochemistry	**Worcester, MA**

ADDITIONAL TRAINING

On-Site Courses by Quintiles Consulting, May 2000
INSTRUCTOR: Kenneth E. Imler, Senior Quality Systems Associate

- FDA Quality Systems Regulation: A guide to understanding and implementing the requirements
- Design Control: A guide to implementing the practices and understanding the requirements

INSTRUCTOR: John E. Wiskerchen, Senior Consultant

- cGMPs 21 CFR Part 211

PATENTS

1. Coleman, T.P. and Peterson, D.L. (1999) "Advanced Antigen Presentation Platform" (Pending)
2. Janciauskiene, S., Du, Z., and Coleman, T.P. (2000) "Method and Composition for Modulating Reverse Lipid Transport" (Pending)
3. Coleman, T.P. and Peterson, D.L. (2001) "Advanced Antigen Presentation Platform" (Pending)

PUBLICATIONS

Coleman, T.P. and Roesser, J.P., (1998) RNA secondary structure: An important cis-element in Rat Calcitonin/CGRP pre-Messenger RNA splicing, Biochemistry, Vol. 37 (45), pp. 15941

INVITED LECTURES AND PANLEIST

1. "Workshop on Entrepreneurial Opportunities" Virginia Commonwealth University October 14, 1999
2. "The convergence of Biotechnology and Information Technology" Virginia Biotechnology Association October 22-23, 2001
3. Presented business opportunity to a large number of venture capital firms a partial list include: Intersouth partners (SC), Aurora (SC), Noro-Mosely (GA), Tall Oaks (VA), Eno River (SC), CE Unterberg Towbin (CO), and Rivervest (MO).

PROFESSIONAL GOALS

1. Bring a company public as a senior executive.
2. Launch a multi-million dollar therapeutic product.
3. Work with or create an entity to whose mission is start and develop world class biotechnology companies.